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June 27, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. 00D-1197

Dear Sir/Madam:

Mutual Pharmaceutical Company wishes to comment on the guidance for industry entitled "Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act."

Mutual Pharmaceutical Company supports the guidance as written. We do not recommend any changes to FDA's application of the ANDA approval provisions and the 180-day exclusivity provisions as stated in the guidance.

However, Mutual does recommend that, upon final implementation of this guidance, the Agency conducts workshops or participates in industry seminars to discuss and clarify the guidance. This is a confusing topic, which has been made even more so by recent, and sometimes contradictory, court decisions and the Agency's responses to those decisions. A clear and complete understanding of how the FDA intends to implement the 180-day exclusivity provisions, under various scenarios, is critical to those generic pharmaceutical companies that submit ANDAs containing Paragraph IV certifications.

Thank you for the opportunity to comment on this guidance.

Sincerely,

Robert Dettery
Vice President, Regulatory Affairs

00D-1197

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